

**Traditional 510(k) Premarket Notification
Summary of Safety and Effectiveness**

APR - 5 2011

K100262 p 1 of 2

Submitter Information	Noble Marketing Jeff Baker President & CEO 100 East Pine Street, Suite 305 Orlando, FL 32801			
Contact Person	Allison Scott, RAC Regulatory Consultant 317-569-9500 x106 317-569-9520 (fax) ascott@ansongroup.com			
Date	March 30, 2011			
Trade Name	Sharps Container			
Common Name	Container, Sharps			
Classification Name	MMK			
Classification Number	21 CFR 880.5570			
Predicate Devices	GongDong	K082042	MMK	880.5570
Device Description	The Noble Sharps Container are intended to be used at healthcare facilities, including nursing stations, medication carts, laboratories, emergency rooms, treatment rooms, and other small quantity waste generators for the safe disposal of hazardous sharps.			
Intended Use	The Noble Sharps container is a disposable over the counter sharps container that is intended for the safe disposal of used medical sharps. It is intended for use in offices, exam and patient rooms of small quantity healthcare providers such as medical doctors, dentists, and veterinarians. The size of the Sharps Container is 6 7/16" in height x 4 15/16" in width x 2 7/16" in depth. It is designed with 4- individual single use chambers with each holding 1-sharp, with a maximum sharp length of 6 1/8".			
Summary	The Nobles Sharps Container is a single use device designed for the safe disposal of hazardous sharps. It is designed with 4-chambers, each chamber will hold one sharps. After each chamber is filled with a sharp, a locking lid is closed by pressing downward, thus permanently sealing the sharps inside the container. All materials including the bottom, sides, and locking lid are manufactured using PP7726 (polypropylene) the same material used in the predicate device, the GongDong disposable sharps container cleared under K082042. The size of the Noble Sharps Container is 6 7/16" in height, 4 15/16" in width and 2 7/16" in depth. The Noble Sharps Container proves to be substantially equivalent to the predicate device.			

Comparison to Predicate Devices

The Sharps Container is similar to the predicate in intended use, materials, measuring principle and performance.

	Noble Sharps Container	GongDong Disposable Sharp Container
510(k) Number	K100262	K082042
Product Code	MMK	MMK
Indication for Use	<ul style="list-style-type: none"> • Single Use Healthcare Sharps 	<ul style="list-style-type: none"> • Single Use Healthcare sharps
Target Population	<ul style="list-style-type: none"> • Healthcare professional 	<ul style="list-style-type: none"> • Healthcare professional
Where used	<ul style="list-style-type: none"> • Healthcare facilities/labs 	<ul style="list-style-type: none"> • Healthcare facilities/labs
Construction	<ul style="list-style-type: none"> • Injection molded 	<ul style="list-style-type: none"> • Injection molded
Materials	<ul style="list-style-type: none"> • Polypropylene 	<ul style="list-style-type: none"> • Polypropylene
Lid	<ul style="list-style-type: none"> • Closure by pressing down on lid secure 	<ul style="list-style-type: none"> • Closure by pressing down on lid to secure
Needle elimination	<ul style="list-style-type: none"> • By vertical dropping 	<ul style="list-style-type: none"> • By vertical dropping

Technological Characteristics

Similar to other sharps containers on the market, sharps are inserted through the top in a vertical position with the sharp side down through the hole in which the sharp is inserted. A lid is then closed by pressing the lid downward for permanent closure and containment of sharps.

Performance of Non-Clinical

The Noble Sharps container subjected to puncture resistance testing per ASTM F 2132, topple resistance testing per CSA Z316.6-07, and leakage tests per BS 7320:1990. Noble Sharps Container proves to be substantially equivalent to currently marketed sharps containers.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room - WO66-G609
Silver Spring, MD 20993-0002

Noble Marketing
C/O Mr. Mark Job
Responsible third party Official
Regulatory Technology Services, LLC
1394 25th Street NW
Buffalo, Minnesota 55313

APR - 5 2011

Re: K110262
Trade/Device Name: Sharps Container
Regulation Number: 21 CFR 880.5570
Regulation Name: Hypodermic Single Lumen Needle
Regulatory Class: II
Product Code: MMK
Dated: March 24, 2011
Received: March 25, 2011

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

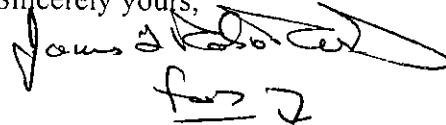
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to <http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address <http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Anthony D. Watson", with a stylized flourish underneath.

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number: K110262

Device Name: Sharps Container

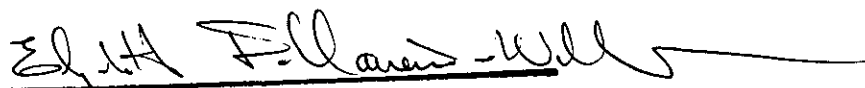
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Prescription Use _____ AND/OR Over-The-Counter Use X
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)

Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

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